REMARKS

The applicant acknowledges the Office Action of 31 December 2008 with appreciation. Claims 11 through 23 remain under consideration. The Office acknowledges the perfected basis under 35 USC § 371 in the copending PCT international application no. PCT/FR03/00200 of 22 January 2003. Acknowledgement of the priority claim to French Application No. 02 00790 of 23 January 2002 under 35 USC § 119, which priority claim was made and perfected by the filing of a certified copy of the priority document and certified translation thereof at the time of the filing of the instant application, is respectfully solicited.

Claim 16 is rejected for lack of written description and enablement under 35 USC § 112, first and second paragraphs, respectively. It is the position of the Office that Claim 16 lacks written description for flow agents generally and that Claim 16 is unclear with respect to the provision of lubricants. The Office acknowledges the specificational disclosure of colloidal silica as a flow agent. With the instant response, the applicant amends the claim to provide for "a flow agent which is colloidal silica". Moreover, the application provides proper punctuation to clarify that the composition comprises "...one or more lubricants, and a flow agent..." It is submitted that these amendments are responsive to the Office rejections.

All claims are rejected under 35 USC § 103(a) for obviousness based on the disclosure of Luhn (US Patent No. 6,770,368) in view of the Wikipedia® Perindopril Product Information Disclosure.

To begin, the applicant acknowledges that the last filed Declaration under 35 USC § 103(c) was completely successful, disqualifying the disclosure of Serpelloni (US Patent No. 7,201,922) as prior art.

With the disqualifying of Serpelloni, the Office reconsidered the bases for rejection and came to the conclusion that, while the earlier rejection for Obviousness under 35 USC § 103 in view of Luhn was withdrawn, upon reconsideration of the claims, it was determined that since Luhn discloses the same lactose/starch granules, tablets made according to the instant invention may be assumed to possess the same functional, i.e., orodispersible, limitation. The Office concludes that the burden is now on the applicant to demonstrate actual functional differences between the tablets of Luhn and those of the instant invention.

In substantiating the rejection in view of the Luhn disclosure, the Office observes that the patent discloses granules of lactose and starch in Column 2 at line 38, that Example 2 discloses rapidly dissolving tablets ("which dissolve in less than 3 minutes and preferably in less than 1 minute") with a hardness within the instant claimed range of 15-50N, tablets comprising magnesium stearate as lubricant, and granule production through co-drying at Column 3, line 44.

The Office relies on Wikipedia for the disclosure that perindopril may be used as an ACE inhibitor and, consequently, may be formulated in the tablets as described in Luhn for the treatment of high blood pressure.

The applicant acknowledged the Office exposition of the cited art, but notes that Luhn discloses granules consisting of lactose and starch with a tableting capacity which results in a tablet hardness greater than 70 N. Luhn also discloses (at column 4) that this tablet hardness distinguishes the disclosed compositions over prior art products. Luhn discloses that the granules possess this tableting capacity while preserving disintegrating properties, which disintegration properties Luhn characterizes as being "in the gastric medium" (col. 1, lines 30-32).

Moreover, the applicant notes that one skilled in the art would recognize that a gastric medium is characterized by a pH less than 2.5 and a volume greater than 25 mL and that an oral medium is characterized by a pH between 5.5 and 6.5 and a volume less than 1 mL. Therefore, one skilled in the art would also recognize that the disintegration properties of a tablet in a gastric medium may not be extrapolated to an oral medium and that a conventional immediate release tablet which exhibits good disintegration properties in the gastric medium does not necessarily exhibit orodispersible properties, consisting of rapid dispersion in the mouth, before such a tablet has been swallowed.

Finally, the Office seems to allege that Luhn discloses a dissolution profile in Example 2 of "less than 3 minutes and preferably less than 1 minute." See the Office Action at page 4. This is simply not the case. At best, Luhn discloses disintegration in at least 56 minutes in a gastric medium. See the table in Column 6 and the disclosure in column 1, lines 30-33. It is well settled that to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. In re Royka, 180 USPQ 580 (CCPA 1974). Clearly, the Office allegation of this limitation which is in Claims 2 and 3 is neither disclosed in the art, nor is it within the general teaching of the cited art.

Thus, the applicant submits that there is nothing in the Luhn disclosure to suggest that co-dried granules consisting of lactose and starch would impart rapid release characteristics to an orodispersible pharmaceutical composition. Luhn equates the "good tableting capacity" associated with the disclosed granules with the ability of the granules to be made into a tablet with a hardness of greater than 70 N for use "in the gastric medium." Moreover, the Office reference to Example 2 for disclosure of rapid disintegration is not commensurate with the instant claims, the most rapid disclosed disintegration being 56 minutes. The instant solid, orodispersible compositions are characterized by low friability and a lower tablet hardness which allows for rapid disintegration in the oral

cavity, i.e., the dosage forms were never intended for a gastric medium. Therefore, the applicant submits that, in fact, the Luhn reference actually teaches away from the instant solid, orodispersible compositions. Reconsideration and withdrawal of the instant rejection for Obviousness is respectfully solicited.

The applicant notes the provisional obviousness type double patenting rejections. Without acknowledging the propriety thereof, the applicants defer consideration of such rejections pending the identification of allowable subject matter.

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Accordingly, entry of the present amendment, reconsideration of all grounds of objection and rejection, withdrawal thereof, and passage of this application to issue are all hereby respectfully solicited.

It should be apparent that the undersigned attorney has made an earnest effort to place this application into condition for immediate allowance. If he can be of assistance to the Examiner in the elimination of any possibly-outstanding insignificant impediment to an immediate allowance, the Examiner is respectfully invited to call him at his below-listed number for such purpose.

Allowance is solicited.

Respectfully submitted,

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Extension fee of $1110.00 for three (3) month extension (Check No. 77225),
Listing of Claims.

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THE COMMISSIONER IS HEREBY AUTHORIZED TO CHARGE ANY FURTHER OR ADDITIONAL FEES WHICH MAY BE REQUIRED (DUE TO OMISSION, DEFICIENCY, OR OTHERWISE), OR TO CREDIT ANY OVERPAYMENT, TO DEPOSIT ACCOUNT NO. 08,3220.